

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

OsteoCox 57 mg chewable tablets for dogs

Firocoxib

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each chewable tablet contains:

Active substances:

Firocoxib 57 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose Monohydrate
Microcrystalline Cellulose
Hickory Smoke Flavour
Hydroxypropylcellulose low-substituted
Croscarmellose Sodium
Magnesium Stearate
Caramel (E150d)
Silica, colloidal anhydrous
Yellow iron oxide (E172)
Red iron oxide (E172)

Tan brown round convex tablets of 10mm diameter with a cross-shaped break line on one side.

The tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs

3.2 Indications for use for each target species

For the relief of pain and inflammation associated with osteoarthritis in dogs.
For the relief of post-operative pain and inflammation associated with soft-tissue, orthopaedic and dental surgery in dogs.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in pregnant or lactating bitches.

Do not use in animals less than 10 weeks of age or less than 3 kg body weight.

Do not use in animals suffering from gastrointestinal bleeding, blood dyscrasia or haemorrhagic disorders.

Do not use concomitantly with corticosteroids or other non-steroidal anti-inflammatory drugs (NSAIDs).

3.4 Special warnings for each target species

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The recommended dose should not be exceeded.

Use in very young animals, or animals with suspected or confirmed impairment of renal, cardiac or hepatic function may involve additional risk. If such use cannot be avoided, those dogs require careful veterinary monitoring.

Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Use this product under strict veterinary monitoring where there is a risk of gastrointestinal bleeding, or if the animal previously displayed intolerance to NSAIDs. Renal and/or hepatic disorders have been reported in very rare cases in dogs administered the recommended treatment dose. It is possible that a proportion of such cases had sub-clinical renal or hepatic disease prior to the commencement of therapy. Therefore, appropriate laboratory testing to establish baseline renal or hepatic biochemistry parameters is recommended prior to and periodically during administration.

The treatment should be discontinued if any of these signs are observed: repeated diarrhoea, vomiting, faecal occult blood, sudden weight loss, anorexia, lethargy, degradation of renal or hepatic biochemistry parameters.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product can cause hypersensitivity (allergic) reactions. People with a known hypersensitivity to non-steroidal anti-inflammatory drugs (NSAIDs) should avoid contact with the product.

This product may be harmful following accidental ingestion.

Care should be taken to avoid accidental ingestion.

In order to prevent children from accessing the product, tablets should be administered and stored out of sight of children.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Divided tablets should be returned to the open blister and inserted into the outer carton.

Laboratory studies in rats and rabbits have shown evidence that firocoxib has the potential to effect reproduction and to induce malformation in fetuses. Pregnant women or those attempting to conceive should administer the product with caution.

Wash hands after use of the product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Target species: Dogs

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting ¹ , Diarrhoea ¹
Rare (1 to 10 animals / 10,000 animals treated):	Nervous system disorder
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Renal disorder Hepatic disorder

¹: Generally transitory in nature and reversible when the treatment is stopped.

As with other NSAIDs, serious adverse events can occur and, in very rare cases, may be fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use in pregnant or lactating bitches.

Laboratory studies in rabbits have shown evidence of maternotoxic and foetotoxic effects at dose rates approximating the recommended treatment dose for the dog.

3.8 Interaction with other medicinal products and other forms of interaction

Pre-treatment with other anti-inflammatory substances may result in additional or increased adverse events and accordingly a treatment-free period with such drugs should be observed for at least 24 hours before the commencement of treatment with the veterinary medicinal product. The treatment-free period, however, should take into account the pharmacokinetic properties of the medicinal products used previously.

The veterinary medicinal product must not be administered in conjunction with other NSAIDs or glucocorticosteroids. Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given NSAIDs.

Concomitant treatment with molecules displaying action on renal flow, e.g. diuretics or Angiotensin Converting Enzyme (ACE) inhibitors, should be subject to clinical monitoring. Concurrent administration of potentially nephrotoxic medicinal products should be avoided as there might be an increased risk of renal toxicity. As anaesthetic medicinal products may affect renal perfusion, the use of parenteral fluid therapy during surgery should be considered to decrease potential renal complications when using NSAIDs peri-operatively.

Concurrent use of other active substances that have a high degree of protein binding may compete with firocoxib for binding and thus lead to toxic effects.

3.9 Amount(s) to be administered and administration route

Oral use.

Tablets can be administered with or without food.

Osteoarthritis:

Administer 5 mg per kg bodyweight once daily as presented in the table below. Duration of treatment will be dependent on the response observed. As field studies were limited to 90 days, longer-term treatment should be considered carefully and regular monitoring undertaken by the veterinarian.

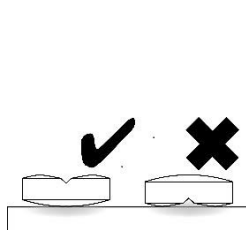
Relief of post-operative pain:

Administer 5 mg per kg bodyweight once daily for up to 3 days as needed, starting approximately 2 hours prior to surgery.

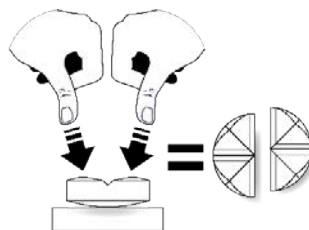
Following orthopaedic surgery and depending on the response observed, treatment using the same daily dosing schedule may be continued after the first 3 days, upon judgement of the attending veterinarian.

Body weight (kg)	Number of chewable tablets by size		mg/kg range
	57 mg	227 mg	
3.0 – 5.5	0.5		5.2 – 9.5
5.6 – 7.5	0.75		5.7 – 7.6
7.6 – 10	1.0		5.7 – 7.5
10.1 – 13	1.25		5.5 – 7.1
13.1 – 16	1.5		5.3 – 6.5
16.1 – 18.5	1.75		5.4 – 6.2
18.6 – 22.5		0.5	5.0 – 6.1
22.6 – 34		0.75	5.0 – 7.5
34.1 – 45		1.0	5.0 – 6.7
45.1 – 56		1.25	5.1 – 6.3
56.1 – 68		1.5	5.0 – 6.1
68.1 – 79		1.75	5.0 – 5.8
79.1 – 90		2	5.0 – 5.7

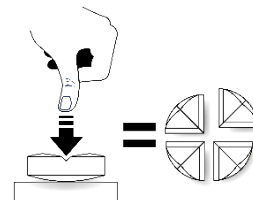
Tablets can be divided into 2 or 4 equal parts to enable accurate dosing.



Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.



To split into 2 equal parts:
Press your thumbs down on both sides of the tablet



To split into 4 equal parts:
Press your thumbs down on both sides of the tablet

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In dogs ten weeks of age, at the start of treatment, at dose rates equal or greater to 25 mg/kg/day (5 times the recommended dose) for three months, the following signs of toxicity were observed: bodyweight loss, poor appetite, changes in the liver (accumulation of lipid), brain (vacuolisation), duodenum (ulcers) and death.

At dose rates equal or greater to 15 mg/kg/day (3 times the recommended dose) for six months, similar clinical signs were observed, albeit that the severity and frequency were less and duodenal ulcers were absent.

In those target animal safety studies, clinical signs of toxicity were reversible in some dogs following cessation of therapy.

In dogs seven months of age, at the start of treatment, at dose rates greater than or equal to 25 mg/kg/day (5 times the recommended dose) for six months, gastrointestinal adverse events, i.e. vomiting were observed.

Overdose studies were not conducted in animals over 14 months of age.

If clinical signs of overdosing are observed, discontinue treatment.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period(s)

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATC vet code: QM01AH90

4.2 Pharmacodynamics

Firocoxib is a non-steroidal anti-inflammatory drug (NSAID) belonging to the Coxib group, which acts by selective inhibition of cyclooxygenase-2 (COX-2) – mediated prostaglandin synthesis. Cyclooxygenase is responsible for generation of prostaglandins. COX-2 is the isoform of the enzyme that has been shown to be induced by pro-inflammatory stimuli and has been postulated to be primarily responsible for the synthesis of prostanoid mediators of pain, inflammation, and fever. Coxibs therefore display analgesic, anti-inflammatory and antipyretic properties.

COX-2 is also thought to be involved in ovulation, implantation and closure of the *ductus arteriosus*, and central nervous system functions (fever induction, pain perception and cognitive function). In *in-vitro* canine whole blood assays, firocoxib exhibits approximately 380-fold selectivity for COX-2 over COX-1. The concentration of firocoxib required to inhibit 50% of the COX-2 enzyme (i.e., the IC₅₀) is 0.16 ($\pm$ 0.05) μ M, whereas the IC₅₀ for COX-1 is 56 ($\pm$ 7) μ M.

4.3 Pharmacokinetics

Following oral administration in dogs at the recommended dose of 5 mg per kg of bodyweight, firocoxib is rapidly absorbed and the time to maximal concentration (T_{max}) is 1.25 ($\pm$ 0.85) hours. The peak concentration (C_{max}) is 0.52 ($\pm$ 0.22) μ g/ml (equivalent to approximately 1.5 μ M), area under the curve (AUC 0-24) is 4.63 ($\pm$ 1.91) μ g x hr/ml, and oral bioavailability is 36.9 ($\pm$ 20.4) percent. The elimination half-life (t_{1/2}) is 7.59 ($\pm$ 1.53) hours. Firocoxib is approximately 96 % bound to plasma proteins. Following multiple oral administrations, the steady state is reached by the third daily dose. Firocoxib is metabolised predominantly by dealkylation and glucuronidation in the liver. Elimination is principally in the bile and gastrointestinal tract.

5. PHARMACEUTICAL PARTICULARS

5.1 Major Incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Return part used tablets to the blister and use within 28 days.

5.3 Special precautions for storage

Store in the original package in order to protect from light.

5.4 Nature and composition of immediate packaging

The tablets are provided in blisters of PVC/PVDC (250/60) with a 20 micron aluminium foil.

Pack sizes:

- 1 cardboard box containing 1 blister of 10 tablets (10 tablets).
- 1 cardboard box containing 3 blisters of 10 tablets (30 tablets).

- 1 cardboard box containing 6 blisters of 10 tablets (60 tablets).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd

7. MARKETING AUTHORISATION NUMBERS

UK(GB) Vm 08749/5034

UK(NI) Vm 08749/3000

8. DATE OF FIRST AUTHORISATION

28 February 2025

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Gavin Hall
Approved: 28 March 2025